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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,762	03/19/2001	Virginia Goss Tusher	M-10523 US	8102

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EXAMINER
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CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/811,762	TUSHER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 28-30, 33, 44, 46, 58 and 60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 28-30, 33, 44, 46, 58 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/2/02</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicants' arguments, filed 24 January 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-22, 28-30, 33, 44, 46, 58 and 60 are currently pending. Claims 23-27, 31, 32, 34-43, 45, 47-57, 59 and 61-64 have been cancelled.

### **Information Disclosure Statement**

The Information Disclosure Statement filed 2 August 2002 has been considered. A signed copy of PTO Form 1449 is included in this Office Action.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 28-30, 33, 44, 46, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The claims now recite “genes or proteins”. However, there is no support in the specification for a method for analyzing a plurality of sets of values associated with a plurality of proteins. There is only support for a method for analyzing a plurality of sets of values associated with a plurality of genes, as originally recited. Applicant points to supposed support for the new claim limitation, however, the support given defines “levels of protein encoded by genes” to be values associated with those genes. The specification does not provide support anywhere for the analysis of *values* (emphasis added) associated with one or more proteins, nor for adjusting parameters of a plurality of proteins, as recited in the instant claims.

**Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Non-Statutory***

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action.

Applicant argues that “the independent claims have been amended to improve clarity and are believed to be directed to statutory subject matter”. Specifically Applicant argues that “the term “gene expression” is commonly used in biotechnology” and that “associated values” refer to biological characteristics and that somehow the “manipulation of associated values represents real world objects and not abstract concepts”. This is not persuasive.

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As related in the previous Office Action, the method analyzing a plurality of sets of values is only a compilation or arrangement of data. Not all processes are statutory under 35 USC 101, as put forth in *Schrader*, 22 F.3d at 296, 30 USPQ2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technical arts is either disclosed in the specification or would have been known to the skilled artisan or (B) be limited to a practical application within the technological arts.

Applicant argues that the “rejected claims comprise a process that manipulates associated values which represent real world objects and not merely abstract concepts or mathematical quantities. Hence, the rejected claims involve the manipulation of data representing physical objects or activities (page 11, lines 23-28)”. This is not persuasive because the instant claims fail to recite a physical transformation outside of the computer. If this is not provided, as recited above, the claims must be limited to a practical application within the technological arts. The claims are directed to pre-processing steps in which no physical transformation is recited.

As the claims fail to recite either a physical step or a “practical application”, i.e. a concrete, tangible, and physical result, the Examiner maintains that the claims are directed to nonstatutory subject matter.

### *Utility*

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible utility or, in the alternative, a well established utility, for the reasons set forth in the previous Office Action.

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Applicant argues that “the specific utilities include identification of genes whose DNA has been damaged by radiation, the identification of genes in tumors, or the identification of genes whose expression correlates with survival time of patients”. This is not persuasive, as the instant claims do not recite steps that are applicable to any of these uses. There is no adequate nexus between the disclosed subject matter and these asserted utilities.

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons set forth in the previous Office Action.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-7, 16, 17, 28, 44, 58 and 60 are rejected under 35 U.S.C. 102 (a) and 102 (e) as being anticipated by WO 99/58720 (Scherer) (IDS filed 8/2/02 Reference B3).

The instant claims are drawn to a method and system for analyzing a plurality of sets of values associated with gene and proteins to identify genes and proteins whose associated values differ by an amount of statistical significance.

Scherer teaches a method and system to quantify the relatedness of a first and second gene expression profile. In regard to claims 1, 3, 4, 5, and 6 Scherer teaches identifying genes whose expression levels (associated values) differ upon comparison. A relative expression score for each pair of first and second gene expression signals is formulated and a pair-wise comparison made to assess relatedness of the two profiles (page 9, lines 4-15). Statistical analysis is performed in a number of ways, as described on page 23, lines 10-16). Background is control and normalization performed to adjust the parameters for independent of the scatter (pages 23-27).

In regard to claim 2, Scherer teaches the assessment of mean gene expression among subsets (page 30, lines 11-23).

In regard to claim 7, Scherer teaches generation of scatter values (Figure 2).

In regard to claims 16 and 17, Scherer teaches comparative analysis of each signal value (page 30, lines 30-32 to page 31, lines 1-3) and variance within and between sets (pages 27-30).

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In regard to claims 44, 58, and 60, the computer element of the instant claims is taught at page 14, lines 3-34 and page 22, lines 32 and 33, for example.

No claims are allowed

### **Conclusion**

The outstanding rejection under 35 USC 112, 2<sup>nd</sup> paragraph has been withdrawn in view of Applicant's response.

The outstanding rejection under 35 USC 102 (a) and (e) over Amerson has been withdrawn in view of Applicant's response.

A new rejection under 35 USC 112, 1<sup>st</sup> paragraph (new matter) has been applied.

The rejections under 35 USC 101, non-statutory and lack of utility are maintained.

A new rejection under 35 USC 102 (a) and (e) has been applied citing WO 99/58720.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the



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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 15, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*4/18/05*